

Remarks/Arguments:

I. Status

The Office Action mailed on June 9, 2009 (the "Office Action"), has been carefully reviewed. Claims 24 and 28 have been amended and new claims 37-43 added. Accordingly, claims 17-43 are pending in this application and claims 17-23 have been withdrawn from examination. Reconsideration of this application is respectfully requested.

II. 35 U.S.C. §112 Rejection and Drawing Objections

Claims 24-27, 33 and 34 were rejected under 35 U.S.C. §112 as failing to comply with the written description requirement on the grounds that the limitations previously added at lines 9-13 of claim 24 lacked support in the specification or drawings. An objection was also lodged with respect to the drawings for failing to show every limitation recited in the claims, namely the limitations in the cited portion of claim 24. Claim 24 has been amended to remove this language so it is believed that the drawing objections and §112 rejection are now moot.

III. 35 U.S.C. §101 Rejections

Claims 24-36 were rejected under 35 U.S.C. §101 as being drawn to non-statutory subject matter. This rejection is premised on the use of terms such as "femur facing side" and "tibia facing side". The terms that form the basis of this rejection are not positive recitations of parts of a human, but are instead adjectives or modifiers to identify surfaces or sides of the claimed positioning member. Claims 24 and 28, where these terms are introduced, do not cover a human being or any part of a human being. The systems

recited in these claims are intended for use in a human but cause any of the claims to run afoul of the non-statutory subject matter limitations of the Patent Statute. It should be noted that the suggested "redefinition" of these terms set forth in the Office Action (p. 4, lines 2-4) also refer to parts of the human body. The suggestion to use the expression "a side configured to face a tibia" is no different than Applicant's language "a tibia facing side". Neither recites part of a human and neither violates 35 U.S.C. §101. Applicant thus requests withdrawal of the rejection under 35 U.S.C. §101.

IV. Claims 25, 26, 29 and 30

Claims 25, 26, 29 and 30 were not subject to a rejection based on prior art. The only rejection noted for these claims was under 35 U.S.C. §§101 and 112. As explained above, the §101 is believed to be improper.

Applicant has presented a new claim 37 that incorporates the limitations of independent claim 24 prior to the addition of the language at lines 9-13, and the limitations of dependent claim 25. New dependent claim 38 includes the limitations of claim 25. The language of new independent claim 37 does not include the language identified as objectionable under 35 U.S.C. §112, but does include the language of claim 25 that was apparently found to be patentable over the prior art of record. It is thus believed that new independent claim 37, along with its new dependent claims 38-40, are in condition for allowance.

Applicant has also presented a new independent claim 41 that incorporates the limitations of independent claim 28 and its dependent claim 29. New dependent claim 42 includes the limitations of claim 30. These new claims 41 and 42 thus recite limitations that were apparently found to be patentable over the cited art. It is thus believed that new

independent claim 41, along with its new dependent claims 42-43, are in condition for allowance.

V. 35 U.S.C. §102 Rejections

Claims 24, 33 and 34 were rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,653,714 to Dietz (hereinafter "Dietz"), claims 28, 31 and 32 were rejected as being anticipated by U.S. Patent No. 4,738,254 to Buechel. (hereinafter "Buechel"), and claims 28, 35 and 36 were said to be anticipated by U.S. Patent No. 4,487,203 to Androphy ("Androphy"). Reconsideration of these claims in view of the following remarks is respectfully requested.

1. Claim 24

Claim 24, as amended, recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

As amended, claim 24 defines the first and second coupler as configured to permit the augment to be fixed to the positioning member abutting either the femur facing side or the tibia facing side. Support for this limitation is found in the Specification at p. 9, lines 9-25. The Dietz reference was said to incorporate a first coupler (24) and a second coupler (16), which take the form of a sliding dovetail joint as shown in Figure 3 of Dietz. Although it was not specifically identified it appears that the rectangular base 12

is asserted to correspond to the claimed augment, while the guide 10 has been identified as the claimed positioning member.

As shown in Figure 3 of Dietz, the first coupler 24 projects from only one surface of the guide 10. Consequently, the base 12 of Dietz can only abut one surface of the guide 10. If the base and guide are mounted to a femur 1, as shown in Figure 7 of Dietz, then the base 12 can only abut the femur facing surface of the guide 10. The tibia facing surface of the guide 10, as seen in Dietz Figures 1-2, does not include any feature for engaging the base 12. Moreover, the upper face of the guide 10 cannot incorporate any such engagement feature because mounting the base to that surface would interfere with the operation of the inner frame 28 (Figure 5) and the milling tool 6 (Figure 7).

Thus, it can be appreciated that the Dietz apparatus does not include first and second couplers that cooperate to fix an augment to a positioning member "abutting either said femur facing side or said tibia facing side." Dietz cannot anticipate claim 24 or its dependent claims 33 and 34 because it does not disclose every limitation of independent claim 24, as amended. With respect to claim 34 it was asserted that Dietz discloses an augment having a contoured lower surface. The lower surface of the base 12 of Dietz is flat and lacks any contour, as shown in Figure 7. Moreover, the lower surface of the base 12 cannot include any contour because it is mounted on a foot 18 that is fixed to the resected surface of the bone. Thus, claim 34 is patentable over Dietz on its own merits.

2. Claim 28

Claim 28 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

an intramedullary pin received within said guide slot of said positioning member of said instrument.

The Buechel Patent

The Buechel reference was said to disclose an intramedullary pin (14), a first coupler (52), a guide slot (39) and a second coupler (76). The positioning member was not specifically identified in Buechel, but based on the assertion of the slot 52 as constituting the "first coupler" it appears that the main body 12 is alleged to be the claimed "positioning member". Likewise, the augment was not specifically identified in the Office Action. If the second coupler is the connector plate 76, then the rejection must be premised on the femoral guide positioner 20 as constituting the claimed "augment".

The structure shown in Buechel is essentially the apparatus identified as prior art in FIG. 2 of the present application. The femoral guide positioner 20 is not an augment, as that term is understood in the art. In a typical procedure, an augment would engage the positioner 20 of Buechel to provide a correct gap, as explained in the present specification.

In order to more fully clarify the claimed invention, claim 28 has been amended to define the couplers as fixing the augment to the positioning member "abutting either the femur facing side or the tibia facing side." Even if the positioner 20 of Buechel is considered to be an augment, it is clear that the positioner 20 does not abut any surface of

the main body 12 facing a bone. Instead, as shown in Figure 9 of Buechel, the positioner interfaces with (but does not abut) the outer face of the main body 12.

Since Buechel does not include every limitation of amended claim 28 it cannot anticipate this claim or its dependent claims 31 and 32. It is further noted with respect to claim 31 that the purported first coupler (52) of Buechel is not a bore but a slot, and the second coupler (76) is not a pin but a plate. These unambiguous terms cannot be redefined to support an anticipation rejection. Buechel does not disclose or contemplate a bore and pin arrangement so claim 31 cannot be anticipated.

The Androphy Patent

Claim 28 was also said to be anticipated by Androphy, with particular reference to Figure 7. Androphy is said to disclose an augment (38), an intramedullary pin (34), a positioning member (108) having a first coupler (110) and a guide slot (118), and a second coupler (60) as recited in claim 28. The element 108 of Androphy is a femur bar (col. 7, line 57), so it is believed that a more appropriate designation would be the base 112 as corresponding to the positioning member. In addition, the element 38 is a "front surface" (col. 3, line 55), so it is believed that a more appropriate designation would be the guide member 36.

It is not clear from the Androphy disclosure whether the base 112 abuts the guide member 36. However, assuming that the two components abut, the guide member 36 can only abut one side of the base 112. As shown in Figure 6 of Androphy, this side faces the femur 22. The guide member 36 cannot be reoriented to face the tibia 24 because it would interfere with the engagement of the intramedullary pin 34 to the bore 118 of the base 112.

Since Androphy does not disclose first and second couplers that cooperate so that the "augment" or guide member 36 can abut two bone facing sides of the "positioning member" or base 112, it cannot anticipate independent claim 28 or its dependent claims 35 and 36. It is therefore believed that claims 28, 35 and 36 are patentable over the Androphy reference.

VI. 35 U.S.C. §103 Rejections

Claim 27 was rejected under 35 U.S.C. §103 as being unpatentable over Dietz. Claim 27 depends from amended claim 24. As explained above, Dietz does not anticipate parent claim 24, so this reference cannot serve as a basis for an obviousness rejection of dependent claim 27. Moreover, there is no rational basis for replacing sliding dovetail joint (24, 16) of Dietz with the pin and bore configuration recited in claim 27. There is no structure in the base 12 of Dietz to support a pin of any type that might be able to engage a bore in the guide 10. The structural alternation necessary for the Dietz device to meet the limitations of claim 27 would be significant, if they can be made at all. There is simply no *prima facie* showing of obviousness of claim 27 in view of Dietz, so it is believed that claim 27 is patentable over the art of record.

Claim 31 was rejected as obvious in view of Androphy. As explained above, Androphy does not anticipate parent claim 28, so this reference cannot serve as a basis for an obviousness rejection of dependent claim 31. It is therefore believed that claim 31 is patentable over the cited art.

VII. Conclusion

Applicants respectfully request entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

Respectfully submitted,

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